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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/921,068	08/02/2001	Thomas E. Clemente	1231-219	5827
32905	7590	03/02/2006	EXAMINER	
JONDLE & ASSOCIATES P.C. 858 HAPPY CANYON ROAD SUITE 230 CASTLE ROCK, CO 80108			MCGARRY, SEAN	
			ART UNIT	PAPER NUMBER
			1635	

DATE MAILED: 03/02/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/921,068

Applicant(s)

CLEMENTE ET AL.

Examiner

Sean R. McGarry

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 15 December 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1 and 5-69 is/are pending in the application.
- 4a) Of the above claim(s) 7-66 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1, 5, 6, and 67-69 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.
- ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: \_\_\_\_\_.

### **DETAILED ACTION**

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 12/15/05 has been entered.

Applicant's arguments filed 12/15/05 have been fully considered but they are not persuasive.

Applicants arguments are based on the assertion that the instant method does not require a 3'UTR. The new grounds of rejection set forth below make moot applicants arguments.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 5 and 6 rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter

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which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

Claim 1 has been amended to recite "due to a lack of a 3' terminal sequence. . ."

This limitation adds new matter to the invention since the application as described in the specification as filed is drawn to constructs that have an "absence of appropriate 3' terminal sequence (3'UTR)" (see page 7), or "absence of the normal 3' terminal sequence" (see page 11). The claim as now amended reads on a construct that now lacks a 3' terminal sequence which appears to broaden the scope of the invention to include, for example, circular oligonucleotides. The claims are now not limited to lacking normal or appropriate sequences but to also include lacking a 3' terminal sequence *per se*. If applicant believes the specification as filed provides support for such embodiments applicant is requested to point to such support with particularity.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1,5, 67, and 68 are rejected under 35 U.S.C. 102(e) as being anticipated by Waterhouse et al [US 6,423,885 B1].

Waterhouse et al disclose in claims methods of reducing the phenotypic expression of a nucleic acid of interest by providing unpolyadenylated target specific RNA comprising a target specific nucleotide comprising a nucleotide sequence essentially identical to a nucleic acid of interest in sense orientation into the nucleus of a cell of a eukaryotic organism sequence where the RNA (see columns 7 and 9, for example) is produced by transcription from a chimeric DNA that comprises a promoter (which can be constitutive, inducible, or tissue specific, for example; see columns 16 and 17, for example) operably linked to a sense sequence corresponding to the target nucleic acid. At column 17 it is disclosed that the unpolyadenylated RNA (an RNA lacking normal 3' terminal sequence) can be expressed from a chimeric construct comprising a target specific DNA region operably linked to a plant expressible promoter and linked to a DNA region comprising a 3' end formation signal but not a polyadenylation signal.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 6 and 69 are rejected under 35 U.S.C. 103(a) as being unpatentable over Waterhouse et al as applied to claims 1, 5, 67, and 68 above, and further in view of Taira et al.

Waterhouse et al is relied upon as above and additionally for the teachings at columns 10, 11, and 15. At columns 10-11 it is disclosed that the constructs of the invention can comprise more than one target-specific nucleotide sequence. At column 15 it is disclosed that the constructs can contain target specific nucleotide sequences separated by multiple self cleaving ribozymes to produce several different target specific RNAs. At column 17 it is disclosed that the unpolyadenylated RNA (an RNA lacking normal 3' terminal sequence) can be expressed from a chimeric construct comprising a target specific DNA region operably linked to a plant expressible promoter and linked to a DNA region comprising a 3' end formation signal but not a polyadenylation signal as an alternative method for producing unpolyadenylated RNA via self splicing ribozymes.

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Although clearly embraced within the scope of the disclosure, Waterhouse et al do not specify that the different RNAs containing different target specific sequences are targeted to different genes.

Taira et al. have taught the use of constructs comprising self cleaving ribozymes to make several antisense based molecules from a vector. At column 6 it has been taught that the vectors may contain a number various concatameric units and that each concatameric unit can be targeted to different RNAs.

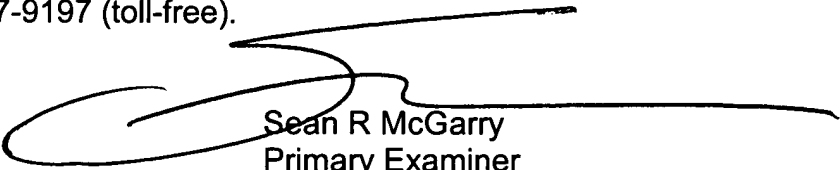
One in the art would clearly have combined the teachings of the prior art to make chimeric vectors as taught by Waterhouse that comprise different target specific RNAs expressed from a chimeric construct comprising a target specific DNA region operably linked to a plant expressible promoter and linked to a DNA region comprising a 3' end formation signal but not a polyadenylation signal as an alternative method for producing unpolyadenylated RNA via self splicing ribozymes where it has been specifically taught by Taira et al that one could clearly include inhibitory RNAs in concatameric constructs. Tiara et al have suggested, for example, that the different RNAs could be targeted to sequences of virus that are known to be different in different strains, for example.

The invention as a whole would therefore have been *prima facie* obvious to one in the art at the time the invention was made.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sean R. McGarry whose telephone number is (571) 272-0761. The examiner can normally be reached on M-Th (6:00-4:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang can be reached on (571) 272-0811. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Sean R McGarry  
Primary Examiner  
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